

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	C.A. No. 21-1015 (GBW)
)	
v.)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
)	
)	
SAREPTA THERAPEUTICS, INC., and)	
THE UNIVERSITY OF WESTERN)	
AUSTRALIA, Defendant and Counter-)	
Plaintiffs)	
)	
v.)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC., Plaintiff and Counter-)	
Defendants.)	

**UNOPPOSED MOTION FOR LEAVE
TO SERVE AMENDED FINAL INFRINGEMENT CONTENTIONS**

Pursuant to Federal Rule of Civil Procedure 16(b)(4) and paragraph 12 of the Scheduling Order (D.I. 143), Plaintiff Nippon Shinyaku Co., Ltd. (“NS”) respectfully moves the Court for leave to serve Amended Final Infringement Contentions.¹ Pursuant to Local Rule 7.1.1, counsel for NS has discussed the proposed Amended Final Infringement Contentions with counsel for Sarepta, and counsel for Sarepta has indicated that Sarepta does not oppose this Motion.

A copy of Plaintiff’s Amended Final Infringement Contentions is attached hereto, and a blackline version of the of the proposed Amended Final Infringement Contentions showing the changes from the prior version is attached hereto as Exhibit 1. As set forth below, there is good

¹ Because the instant Motion is unopposed, NS does not submit a letter brief in support hereof and sets forth the basis for the requested amendment herein.

cause to grant NS leave to serve Amended Final Infringement Contentions and such leave will not prejudice Defendant.

Pursuant to paragraphs 3(e) and 12(a) of the Scheduling Order (D.I. 143), NS served Sarepta with its Final Infringement Contentions on June 22, 2023. The Final Infringement Contentions included allegations related to claims 1 and 6 of U.S. Patent No. 10,683,322 (“the ’322 Patent,” D.I. 2-8), which claim a method of manufacturing an oligonucleotide. Specifically, NS’s Final Infringement Contentions included contentions that Sarepta infringes steps e) and f) of the method claims under the doctrine of equivalents. NS’s proposed Amended Final Infringement Contentions seek to amend and update only NS’s contentions related to Sarepta’s infringement of steps e) and f) of claims 1 and 6 of the ’322 Patent.

There is good cause NS’s Amended Final Infringement Contentions. Since the service of the Final Infringement Contentions on June 22, 2023, additional relevant information related to NS’s contentions with respect to steps e) and f) of claims 1 and 6 of the ’322 Patent has been uncovered. First, on July 3, 2023, the Court issued its claim construction Memorandum Opinion (D.I. 248) and Order (D.I. 249), which specifically construed steps e) and f) of claims 1 and 6 of the ’322 Patent. Second, on July 11, 2023, Sarepta served its Final Non-Infringement Contentions, identifying for the first time an argument that the application of the doctrine of equivalents to steps e) and f) would ensnare the prior art—an issue for which Sarepta bears the burden of production. Third, on July 18, 2023, NS took the deposition of Dr. Jurus Jurayj—Sarepta’s 30(b)(6) witness on topics related to the Sarepta’s manufacturing process as relevant to steps e) and f). Each of these events provided NS with additional, previously unknown information related to its contentions that Sarepta infringes steps e) and f) of claims 1 and 6 of the ’322 Patent under the doctrine of equivalents. NS provided its proposed Amended Infringement Contentions to Sarepta

on July 27, 2023—only two days after it received the final transcript of Dr. Jurayj’s deposition. Accordingly, good cause exists to grant NS leave to serve its Amended Final Infringement Contentions.

Moreover, Sarepta will not be prejudiced by granting NS leave to serve its Amended Final Infringement Contentions. First, NS has assured Sarepta that NS will not oppose any attempt by Sarepta to amend its Noninfringement Contentions solely to respond to NS’s amendment, should Sarepta believe such amendment is needed. Second, opening expert reports are not due until September 5, 2023—providing the parties with sufficient time to allow experts to consider and address any new contentions. And third, Sarepta has stated that it does not oppose NS’s motion, further confirming a lack of prejudice.

Due to the identified good cause and lack of prejudice, NS respectfully requests that the Court grant NS leave to serve Amended Final Infringement Contentions.

Dated: August 4, 2023

Respectfully submitted,

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